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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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| 08/729,343 | 10/16/96 | LEE | D |

| EXAMINER | |
|---|---|
| KULKOSKY, P | |
| ART UNIT | PAPER NUMBER |
| 1502 | 11 |

15M1/0715

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DATE MAILED: 07/15/97

D6,

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1 - 20 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1 - 20 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1 - 20 are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☒ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**



* U.S. GPO: 1996-421-632/40206

Restriction is required between the following distinct and independent inventions, 35 USC 121.

I) Claims 1-16 which are drawn to an implantation method in which poorly crystalline calcium phosphate is used and which is classified in class 606, subclass 76, 77.

II) Claims 17-20 which are drawn to a two-step in which reactive amorphous calcium phosphate is used and which is classified in class 523, subclass 115 and class 423, subclass, 312.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case the product is preparable by other methods in which a second calcium phosphate other than those disclosed is used.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Scozzafava on June 13, 1997 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in responding to this Office action. Claims 17-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

> patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Chow 5,525,148 or C.A. 113:218168J or C.A. 87:73954.

It would be obvious to prepare a "poorly crystalline" calcium phosphate as claimed since the physical structure of same is not defined in such a way as to distinguish over the amorphous calcium phosphates of the cited prior art.

Claims 1-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Nagata et al. 5,427,754 or Palmer et al. 4,849,193 in view of Niwa et al. 4,429,691.

It is considered to be a routine preparation to use a procedure as described in the instant specification working examples since the starting materials and reaction catalysts are equivalent to that used in Nagata et al. or Palmer et al. The implantation system of the claims is considered to be obvious in view of the methods of Niwa et al.

It would be obvious to those in the art to form a poorly crystalline calcium phosphate using the techniques of the primary references and then apply same as instructed in Niwa et al.

Claims 1-16 are rejected under 35 USC 112, paragraph 2.

The claims define a "poorly crystalline" calcium phosphate but the product(s) of the working Examples are not clearly equivalent thereto. Thus, the Applicant ACP product is not identified as the product of a definite chemical process or by an analyzed

chemical structure. The claims do not describe a calcium phosphate product clearly distinguishable from prior art amorphous calcium phosphates.

The method of claim 2 is unclear since the in vivo conversion process is not described in terms of reactants, catalysts, components or conditions necessary to form the poorly crystalline calcium phosphate.

**Peter Kulkosky**:cb
Primary Examiner

Wednesday, July 2, 1997
Friday, July 11, 1997